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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,999	07/18/2003	Ronit Yahalomi	1662/611054	3044

26646 7590 11/09/2005

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/622,999	Applicant(s) YAHALOMI ET AL.	
	Examiner Celia Chang	Art Unit 1625	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1-62 are pending.

2. *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 42, drawn to nateglinide form A and process of making form A, classified in class 562, subclass 445.
- II. Claims 5-8, 44, drawn to nateglinide form M and process of making form M, classified in class 562, subclass 445.
- III. Claims 9-12, 46, drawn to nateglinide form N and process of making form N, classified in class 562, subclass 445.
- IV. Claims 13-19, 49 drawn to nateglinide form Q and process of making form Q, classified in class 562, subclass 445.
- V. Claims 20-27, 48, 51 drawn to nateglinide form Y and process of making form Y, classified in class 562, subclass 445.
- VI. Claims 28-34, 58 drawn to nateglinide form Z and process of making form Z, classified in class 562, subclass 445.
- VII. Claims 35-40, 53-57 drawn to nateglinide form  $\theta$  and process of making form  $\theta$ , classified in class 562, subclass 445.
- VIII. Claim 41 drawn to nateglinide xylene solvate, classified in class 562, subclass 445.
- IX. Claim 43 drawn to nateglinide carbon tetrachloride solvate, classified in class 562, subclass 445.
- X. Claim 45 drawn to nateglinide dichloroethane solvate, classified in class 562, subclass 445.
- XI. Claim 47 drawn to nateglinide chloroform solvate, classified in class 562, subclass 445.
- XII. Claim 50 drawn to nateglinide dichloromethane solvate, classified in class 562, subclass 445.

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XIII. Claim 52 drawn to nateglinide heptane solvate, classified in class 562, subclass 445.

XIV. Claim 59-60 drawn to nateglinide isopropanol/H<sub>2</sub>O solvate, classified in class 562, subclass 445.

Claims 61-62 are generic and can be prosecuted with each groups I-XIV to the extend of each group.

The inventions are distinct, each from the other because:

Groups I-XIV are drawn to different products which must be examined based on the chemical and physical nature as compared to the prior art. The search for polymorphic forms and or solvates are extremely burdensome and are not coextensive of each other. Especially, no standard nomenclature has been appointed for the polymorphs, each individual polymorph must be search for its chemical content and structure together with the many separate physical data for the particular forms.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Nov, 8, 2005*

  
*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*